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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,098	08/24/2001	Eva S. Snitkin	687-401	5775

7590                    02/13/2003

American Medical Systems  
10700 Bren Road West  
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EXAMINER
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ANDERSON, CATHARINE L

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/939,098	SNITKIN ET AL.
Examiner	Art Unit	
C. Lynne Anderson	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-44 is/are pending in the application.
  - 4a) Of the above claim(s) 18-25 and 30-38 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,7-9, 11,26 and 39-44 is/are rejected.
- 7) Claim(s) 2-6, 10, 12-17 and 27-29 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3,6</u> .	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17, 26-29, and 39-44, drawn to an article, classified in class 600, subclass 37.
- II. Claims 18-25 and 30-38, drawn to methods of making an article, classified in class 435, subclass 395.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Jeffery Hohenshell on 31 January 2003 a provisional election was made without traverse to prosecute the invention of the article, claims 1-17, 26-29, and 39-44. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18-25 and 30-38 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 39 discloses a predetermined visual indicia being absent from the mesh material when the sling is free from tension. There is no description in the specification disclosing how one skilled in the art may construct a sling having a predetermined visual indicia that is absent when the sling is free from tension. The specification instead discloses a visual indicia which is present on the mesh when the sling is free from tension, as shown in figure 7A, but adopts a different shape or structure when the sling is exposed to tension, as shown in figure 7B. The claims will be examined in light of the Examiner's interpretation of the invention as described in the specification.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in–  
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1, 7, 8, 11, 26, and 39-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Gellman et al. (6,042,534).

With respect to claim 1, Gellman discloses a surgical sling 10, as shown in figure 1, for insertion into a patient to support the urethra, as described in column 6, lines 33-42. The surgical sling 10 comprises a length of material having a longitudinal axis and a latitudinal axis, as shown in figure 1. The material is elastic, as disclosed in column 7, lines 46-48, and therefore has elongation properties along each axis. The elongation properties will be different from each other due to the difference between the length and width of the material, as shown in figure 1.

With respect to claim 7, the sling is coated with a substance that enhances biocompatibility, as disclosed in column 7, line 65.

With respect to claim 8, the material is used in a surgical setting, and comprises a mesh, as disclosed in column 7, line 49.

With respect to claim 11, the material is impregnated with a therapeutic agent, as disclosed in column 7, lines 61-65.

With respect to claim 26, Gellman discloses a surgical sling 10, as shown in figure 1, for insertion into a patient to support the urethra, as described in column 6, lines 33-42. The sling 10 comprises a plurality of regions along its longitudinal axis, a rectangular central portion and two side portions, each having a trapezoidal shape, as

shown in figure 1. Due to the difference in shapes, these regions will have different elongation properties.

With respect to claim 39, Gellman discloses a sling 10, as shown in figure 1, for use in treating urinary incontinence, as described in column 6, lines 37-40. The sling 10 comprises a mesh material which is elastic, and therefore has predetermined elongation properties, as disclosed in column 7, lines 46-49. The mesh has a predetermined visual indicia 20, as shown in figure 1, which is distorted when the mesh is under tension.

With respect to claim 40, elongation of the mesh in the longitudinal direction will cause the width of the mesh to change, and therefore the visual indicia is a predetermined width of the sling 10.

With respect to claims 41 and 43, the visual indicia 20 is a predetermined geometrical pattern, as shown in figure 1, and described in column 9, lines 58-64.

With respect to claim 42, the predetermined geometrical pattern may be the hole pattern 18, as shown in figure 2.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gellman et al. (6,042,534) as applied to claim 39 above.

Gillman discloses all aspects of the claimed invention with the exception of the visual indicia being a word. The use of printed words is well-known in the art to provide a visual indicia. It would therefore be obvious to one of ordinary skill in the art at the time of invention to make the visual indicia of Gillman a word.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gellman et al. (6,042,534) as applied to claim 8 above, and further in view of Wilkinson et al. (4,403,604).

Gellman discloses all aspects of the claimed invention with the exception of coating the mesh material with silicone.

Wilkinson discloses a surgical sling 10 for implantation into a human body, as shown in figure 1. The sling is comprises of a polyester mesh material that has been coated with silicone to reduce adverse reaction to the sling and facilitate easy removal of the sling, as disclosed in column 4, lines 3-7.

It would therefore be obvious to one of ordinary skill in the art at the time of invention to coat the mesh material of Gellman with silicone, as taught by Wilkinson, in order to reduce adverse reaction to the sling and facilitate easy removal of the sling.

#### ***Allowable Subject Matter***

Claims 2-6, 10-17, and 27-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patents 6,010,447; 6,221,005; 6,306,079 and 6,368,859 pertain to slings adapted for treatment of urinary incontinence.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Lynne Anderson whose telephone number is (703) 306-5716. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

CWA  
cla  
February 10, 2003

  
WEILUN LO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700